510(k) Summary

Proprietary Name:	T2 Tibial Nailing System
Common Name:	Intramedullary Fixation Rod
Classification Name and Reference:	Rod, Fixation, Intramedullary and Accessory 21 CFR §888.3020
Proposed Regulatory Class:	Class II
Product Codes:	HSB
For Information Contact:	Estela Celi, RAC Regulatory Affairs Specialist Stryker Trauma AG 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461; Fax (201) 831-3461
Legally Marketed Devices to Which Substantial Equivalence Is Claimed:	K003018 – Titan Tibial Nail K111667 – Synthes Suprapatellar Insertion Instruments
Date Prepared:	August 30, 2013

OCT 10 2013

Description

This Traditional 510(k) submission is being supplied to the US FDA to include a modified targeter device and its components as Class II accessories as part of the Suprapatellar Instrument (SPI) System included in the T2 Tibial Nailing System, previously cleared under K003018 as the Titan Tibial Nail. The T2 Tibial Nailing System was determined substantially equivalent via 510(k) K003018 and included tibial nails and associated accessories such as locking screws, compression screws and end caps. There are three nail designs for the T2 Tibial Nail: Proximal, Standard, and Distal. These T2 tibial nails are fabricated from titanium and are available sterile. The T2 tibia targeter devices are intended to be used as part of the T2 Tibial Nailing System. In addition, this submission addresses a modification made to some components of the targeting device.

Intended Use

The T2 Tibial Nailing System is intended to provide temporary stabilization of various types of fractures, malunion, and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically, and compression locked.

Indications
The T2 Tibial Nailing System is intended to provide temporary stabilization of various types of fractures, malunion and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

The T2 Tibial Nailing System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthodosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

Summary of Technologies
The subject device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices. Inclusion of the targeter device and its components as accessories to the T2 Tibial Nailing System does not alter the device technology.

Non-Clinical Testing
Non-clinical laboratory testing was performed on the targeting device and its components to determine substantial equivalence. Testing demonstrated that the subject targeter device is substantially equivalent to the predicate device currently cleared for marketing.
The following testing was performed:

- *Stiffness Testing*
- *Bending Load*
- *Transferable Torque of Connections*
- *Transferable Torque between Nail and Nail Adapter*
- *Impulse Test*
- *Drop Test*
- *Cadaveric Testing*

Clinical Testing
Clinical testing was not required for this submission.

Conclusion
The T2 Tibial Nailing System and its components are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

Stryker Trauma AG
Ms. Estela Celi
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K131365
Trade/Device Name: T2 Tibial Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 13, 2013
Received: September 13, 2013

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131365

Device Name: T2 Tibial Nailing System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices